

Approved: XX-XX-09

SUBJECT: CONDUCT AND APPROVAL OF SELECT AGENT WORK AT DEPARTMENT
OF ENERGY SITES

PURPOSE AND SCOPE

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) directs the Secretary of Energy and the Administrator of the National Nuclear Security Administration to expand, enhance, and intensify research relevant to the rapid detection and identification of pathogens likely to be used in a bioterrorism attack or other agents that may cause a public health emergency.

In meeting its obligations under the Public Health Security and Bioterrorism Preparedness and Response Act, the Department of Energy (DOE) places a high priority on occupational health, safety and security, as well as its responsibility for protecting the public and environment from any hazards resulting from these activities.

The purpose of this policy is to establish the Department's expectations for the establishment and operation of biological research laboratories utilizing select agents (as defined by the Center for Disease Control and Prevention or CDC), and to ensure future policy needs for the operation, coordination, and oversight of biological research laboratories.

POLICY

The Department will not authorize any biosafety level (BSL)-4 activity or allow BSL-4 operations to be conducted by or for another federal agency at DOE facilities or on DOE sites.

The Department will oversee and approve the building and operations of any DOE laboratories or other DOE facilities utilizing select agents.

All biological research activities performed by DOE or DOE contractors will comply with all applicable DOE regulations and directives as well as other applicable federal, state, and local regulations.

DOE will establish guidance to ensure safe construction and operation of BSL-3 laboratories. Any new construction of BSL-3 laboratories must be conducted in accordance with DOE O 413.3A, *Program and Project Management for the Acquisition of Capital Assets*, dated 7-28-06.

DOE will develop a long-term strategy for Departmental coordination of current and future research activity involving select agents and ensure a cooperative relationship is developed with the United States Department of Health and Human Services and the United States Department of Agriculture (USDA) in their oversight of DOE select agent activities.

DOE will ensure that any agency requesting work be responsible for all costs incurred by DOE contractor(s) performing work for that agency for which DOE is required to reimburse the contractor(s). Such costs includes any and all third party liability costs incurred by the contractor and reimbursed by DOE in accordance with the Insurance, Litigation and Claims Clause (DEAR 970.5228-1) contained in DOE's contract with the contractor. To the extent that DOE may incur any liabilities in regards to the performance of the work directly, DOE will insure that the agency requesting the work will reimburse DOE for such liabilities.

APPLICABILITY

This Policy applies to DOE and DOE contractors in the development, construction, and operation of biological laboratories utilizing select agents.

RESPONSIBILITIES

1. The head of the Program Secretarial Office (PSO) is responsible for the formal approval of the establishment of any new biological research laboratory capable of conducting research on or otherwise utilizing select agents.
2. Head of DOE field element is responsible for—
 - a. ensuring the full implementation of this policy at the respective field facility and
 - b. being fully informed of all laboratory operations with select agents including those which may be part of classified Work for Others or similar projects.
3. The DOE Biosurety Executive Working Group in concert with the Department of Homeland Security and other federal agencies utilizing DOE laboratories will be responsible for developing a long-term strategy for research activities involving select agents.

REFERENCES

- Public Law 91-190, National Environmental Policy Act (NEPA)
- 7 CFR Part 331, "Possession, Use and Transfer of Select Agents and Toxins"
- 9 CFR Part 121, "Possession, Use and Transfer of Select Agents and Toxins"
- 42 CFR Part 72, "Interstate Shipment of Etiological Agents"
- 42 CFR Part 73, "Select Agents and Toxins"
- 42 CFR Part 1003, "Civil Money Penalties, Assessments and Exclusions"
- 10 CFR Part 851, Worker Safety and Health Program, Appendix A, Sec. 7, Biological Safety

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